

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
CHATTANOOGA DIVISION

CHILDREN’S HEALTH DEF., <i>et al.</i> ,)	
)	
Plaintiffs,)	1:21-CV-00200-DCLC-CHS
)	
vs.)	
)	
FOOD & DRUG ADMIN., <i>et al.</i> ,)	
)	
Defendants.)	
)	

MEMORANDUM OPINION AND ORDER

This matter is before the Court to consider Plaintiff Children’s Health Defense’s (“CHD”) and Amy Miller’s motions for a “stay” [Docs. 9, 14] of Defendant Food and Drug Administration’s (“FDA”) licensure of the Pfizer Comirnaty COVID-19 vaccine and reauthorization of the Pfizer-BioNTech vaccine’s emergency use authorization (“EUA”). Defendants FDA and FDA Acting Commissioner Janet Woodcock oppose Plaintiffs’ motion and have moved to dismiss the case for lack of subject matter jurisdiction [Doc. 22]. The matter has been fully briefed.

I. BACKGROUND

This case concerns the FDA’s licensure of Pfizer’s Comirnaty vaccine and its decision to extend, simultaneously, the Pfizer-BioNTech vaccine’s EUA [Doc. 19, ¶ 1]. Federal law authorizes the Secretary of Health and Human Services to issue EUAs for vaccines under limited circumstances.¹ This permits the immediate use of a vaccine without having to follow the normal

¹ The Secretary of Health and Human Services must find that: (1) the investigational drug, in this case the Pfizer-BioNTech vaccine, is intended to treat “a serious or immediately life-threatening disease”; (2) there is no satisfactory alternative therapy available to treat the disease; (3) the investigational drug is undergoing clinical trials; (4) the sponsor of the clinical trial is

review process. *See* 21 U.S.C. § 360bbb-3. In January 2020, the Secretary of Health and Human Services declared a public health emergency. (<https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>). Since that moment, COVID-19 has wreaked havoc on the country, taking the lives of hundreds of thousands of people. In response, Pfizer, Moderna, and Johnson & Johnson began to research and develop potential vaccines. On December 11, 2020, the FDA issued an EUA for the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age or older pursuant to 21 U.S.C. § 360bbb-3 [Doc. 19, ¶ 15]. On December 19, 2020, it issued an EUA for Moderna’s vaccine, and, on February 27, 2021, it issued an EUA for the Johnson & Johnson vaccine.

In May 2021, CHD filed a Citizen Petition with the FDA requesting it refrain from licensing COVID-19 vaccines and revoke the prior EUAs for the three existing vaccines [*Id.*, ¶ 17]. On August 9, 2021, Secretary of Defense Lloyd Austin advised all Department of Defense employees that he would “seek the President’s approval to make the [COVID-19] vaccines mandatory no later than mid-September, or immediately upon the [FDA’s] licensure, whichever comes first.” Memorandum from Sec’y of Def. Lloyd Austin to Dep’t of Def. employees (Aug. 9, 2021) (available online). Two weeks later on August 23, 2021, the FDA granted a license to Pfizer’s Comirnaty vaccine but not the Pfizer-BioNTech vaccine [*Id.*, ¶ 20]. Although the FDA noted that they were “interchangeable,” it still described them as “legally distinct.” [*Id.*, ¶ 20]. On that same date, the FDA denied CHD’s Citizen Petition.

On August 31, 2021, Plaintiffs CHD, “on behalf of its members who have been affected by the Defendants’ actions,” and Miller filed their initial complaint and later amended their

seeking marketing approval; and (5) there is sufficient evidence of its safety and effectiveness. 21 U.S.C. § 360bbb(c)(1)-(7).

complaint [Docs. 1; 19, ¶ 4]. Plaintiffs asked the Court to enjoin the FDA from both licensing the Pfizer Comirnaty vaccine and extending the EUA for the Pfizer-BioNTech vaccine. Plaintiffs claim that the FDA’s decision to license Pfizer’s Comirnaty vaccine while simultaneously extending the EUA for the Pfizer-BioNTech vaccine violates federal law as EUA designations can only occur when, under 21 U.S.C. § 360bbb-3-(3), the Secretary finds “that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition.” 21 U.S.C. § 360bbb-3-(3)(c)(3). Plaintiffs reason that, once the FDA licensed Pfizer’s Comirnaty vaccine, it had no legal basis to retain EUA status for any of the other vaccines [Doc. 19, ¶¶ 29-30].

They allege that the FDA’s finding of the unavailability of the Comirnaty vaccine in the United States to support the Pfizer-BioNTech vaccine’s continued EUA status is “specious” because, if the vaccines are truly “interchangeable,” then Pfizer could simply relabel their BioNTech vaccine as its licensed Comirnaty vaccine [*Id.*, ¶ 46]. They assert the FDA did not articulate a satisfactory explanation for its decision to license the Pfizer Comirnaty vaccine while extending EUA status to the Pfizer-BioNTech vaccine, rendering its decision arbitrary and capricious and in violation of the Administrative Procedures Act (“APA”), 5 U.S.C. § 706(2)(a) [*Id.*, ¶ 32]. Plaintiffs state that “Pfizer cannot unlawfully reap the benefits of a licensure and EUA status simultaneously” [*Id.*, ¶ 37]. They claim the FDA has given “legal cover for licensed vaccine mandates while gifting Pfizer a bullet-proof liability shield that comes only with an EUA.” [*Id.*, ¶ 45]. They describe this as a “bait-and switch” tactic that permits Pfizer to claim licensure of its Comirnaty vaccine but sell off its inventory of BioNTech vaccines “that enjoy blanket liability protection.” [*Id.*, ¶ 49]. Plaintiffs also allege that the FDA’s licensure of the Comirnaty vaccine has “triggered employer, military, educational and institutional mandates across the

country, coercing millions of healthy individuals to take unwarranted, risky medical interventions.” [*Id.*, ¶ 50]. Plaintiffs seek to have the FDA’s decisions to license the Comirnaty vaccine and reauthorize the Pfizer-BioNTech EUA “vacate[d] and remand[ed],” have attorneys’ fees and costs awarded, and “all other appropriate relief as necessary.” [*Id.*, pg. 12].

In support of its Complaint, Plaintiffs attached the declarations of 15 CHD members who were, or are, presently serving in the United States military [*Id.*, ¶ 18]. The first declaration is from Pam Long, a member of CHD [Doc. 15, pgs. 1-3]. She is a former Army officer and claims she has “an active network of 18,000 people on social media who have shared concerns about the military vaccine mandate.” [*Id.*, pg. 1]. Long alleges that unvaccinated servicemembers, who refuse to comply with the military’s vaccine mandate, are denied access to dining facilities and gyms, have been removed from leadership positions in the military, have been ordered to forfeit their leave, and faced physical, emotional, and professional consequences [*Id.*, pgs. 1-3]. She claims that some have retired rather than be vaccinated [*Id.*, ¶ 16]. Long does not identify any of these servicemembers as members of CHD specifically, and she does not allege that she has suffered such penalties herself [*Id.*, pgs. 1-3].

The remaining 14 declarations are from current servicemembers across all branches of the United States military [*Id.*, pgs. 7-197]. Each declaration details various objections to receiving the vaccine, including religious based objections and concerns regarding the effect the vaccine might have on their ability to have children. They express fear that if they fail to comply with the military’s mandatory vaccination policy, they are in jeopardy of being discharged from the military and losing retirement benefits and their future careers. Many also claim they have filed for religious exemptions from the vaccine mandate but have yet to have their requests addressed. Plaintiffs also include an affidavit from CHD’s general counsel, Mary S. Holland, who states that

the interests of the declarants who “CHD protects are clearly related to CHD’s mission and overarching goals as an organization.” [Doc. 26, pg. 1]. The only individual Plaintiff is Amy Miller who alleges she is at “imminent risk of immediate harm from [the] FDA’s actions to both license and contemporaneously authorize Pfizer vaccines against COVID.” [Doc. 19, ¶ 5].

The FDA and its Commissioner have filed a motion to dismiss, claiming Plaintiffs lack Article III standing [Doc. 23, pg. 6]. They assert that Plaintiff CHD does not claim an injury to itself and that Plaintiff Miller only alleges that she is at imminent risk of immediate harm, without describing how she will be harmed [*Id.*, pg. 6]. They contend that CHD relies on associational standing but fails to plead facts to show that its members would have standing to sue in their own right or that the present suit is related to CHD’s organizational mission [*Id.*, pg. 7]. They argue none of the declarants state they have: (1) suffered a present, or impending, injury-in-fact; (2) shown that the purported harm they face is traceable to Defendants’ conduct; or (3) established that a “stay” would remedy the purported harm. [*Id.*, pgs. 8-12]. They also argue that the present suit is unrelated to CHD’s organizational purpose because the declarants are adult servicemembers interested in evading a vaccine mandate and do not represent the interests of children [*Id.*, pgs. 13-14].²

CHD argues it has associational standing to bring the present suit on behalf of its members [Doc. 25, pgs. 12-17]. Plaintiffs contend that the declarants who are members of CHD have Article III standing to sue in their own right [*Id.*, pgs. 14-15]. They next assert that the present suit is germane to CHD’s purpose because its mission is to “end the childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable, and

² Defendants also make several arguments addressing the merits of Plaintiffs’ claim. [Doc. 23, pgs. 14-23]. Because the Court finds that Plaintiffs lack standing, it declines to consider Defendants’ merits arguments.

establish safeguards so this never happens again.” [*Id.*, pg. 16]. They further explain that CHD “fights to protect all citizens from various forms of public health harm.” [*Id.*]. Plaintiffs contend that the relief sought does not require the participation of individual members [*Id.*, pg. 17]. Plaintiffs also argue that CHD has organizational standing because it must divert resources “due to the threat the FDA’s bait-and-switch imposes on millions of Americans.” [*Id.*]. Plaintiffs next contend that Miller has standing to sue because of the FDA’s denial of CHD’s citizen petition [*Id.*, pg. 18].

II. ANALYSIS

Defendants ask the Court to dismiss Plaintiffs Amended Complaint on the grounds that the Court lacks subject matter jurisdiction under Fed. R. Civ. P 12(b)(1). “A Rule 12(b)(1) motion for lack of subject matter jurisdiction can challenge the sufficiency of the pleading itself (facial attack) or the factual existence of the subject matter jurisdiction (factual attack).” *Cartwright v. Garner*, 751 F.3d 752, 759-60 (6th Cir. 2014) (citing *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir. 1994)). “A facial attack goes to the question of whether the plaintiff has alleged a basis for subject matter jurisdiction, and the court takes the allegations of the complaint as true for purposes of Rule 12(b)(1) analysis,” while “[a] factual attack challenges the factual existence of subject matter jurisdiction.” *Id.* Defendants mount a facial attack on Plaintiffs’ complaint for lack of subject matter jurisdiction under Fed. R. Civ. P. 12(b)(1) because they assume the truth of Plaintiffs’ factual allegations. Thus, the Court’s analysis will focus on determining the sufficiency of Plaintiffs’ pleadings to establish subject matter jurisdiction. *Id.*

Courts “do not have a standalone power to evaluate the constitutionality of every law passed by Congress or every initiative implemented by the President.” *Ass’n of Am. Physicians & Surgeons v. Food & Drug Admin, et al.*, 13 F.4th 531, 536 (6th Cir. 2021). “A court may engage

in such judicial review and issue a remedy regulating the political branches only when necessary in the execution of its duty to decide a case.” *Id.* (internal quotations and citations omitted). “It may not issue an advisory interpretation of the Constitution or an advisory injunction regulating those branches whenever a concerned citizen thinks they have acted unlawfully.” *Id.* Nor should courts “entertain citizen suits to vindicate the public’s nonconcrete interest in the proper administration of the laws.” *Lujan v. Def. of Wildlife*, 504 U.S. 555, 581 (1992) (Kennedy, J., concurring); *United States v. Richardson*, 418 U.S. 166, 192 (1974) (Powell, J., concurring) (reasoning that a court may not take on “ideological disputes about the performance of government”).

“The party invoking federal jurisdiction bears the burden of establishing [standing].” *Lujan*, 504 U.S. at 561. Before the Court are both CHD, an organizational plaintiff, and Miller, an individual plaintiff. CHD, as an association, may “sue over injuries suffered by its members even when (as here) the entity itself alleges no personal injury.” *Ass’n of Am. Physicians & Surgeons*, 13 F.4th at 537. For a group to assert associational standing, it must show that: “(1) its members would otherwise have standing to sue in their own right; (2) the interests that the suit seeks to protect are germane to the organization’s purpose; and (3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Id.* (internal quotations and citations omitted).

The first element of associational standing requires an organization to show “that its members have Article III standing in their own right.” *Id.* at 543. “Standing has three elements: injury, causation, and redressability.” *WCI, Inc. v. Ohio Dep’t of Pub. Safety*, No. 20-3930, 2021 WL 5351864, at *3 (6th Cir. Nov. 17, 2021) (citing *Lujan*, 504 U.S. at 560-61). “An injury is an invasion of a legally protected interest that is concrete and particularized and actual or imminent,

not conjectural or hypothetical.” *Id.* (citations and internal quotations omitted). A threatened injury must be “certainly impending” to constitute an injury for standing purposes. *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 401-02 (2013). “[T]he mere possibility that the injury will arise in the future does not suffice.” *Ass’n of Am. Physicians & Surgeons*, 13 F.4th at 545 (internal quotations omitted). Generalized grievances do not support Article III standing. “A litigant raising only a generally available grievance” by “claiming only harm to his and every citizen’s interest . . . and seeking relief that no more directly and tangibly benefits him than it does the public at large[,] does not” satisfy Article III standing. *In re FirstEnergy Sols. Corp.*, 828 F. App’x 321, 323 (6th Cir. 2020) (quoting *Hollingsworth v. Perry*, 570 U.S. 693, 707 (2013)). “Article III standing is not to be placed in the hands of ‘concerned bystanders,’ who will use it simply as a vehicle for the vindication of value interests.” *Id.*

The injury CHD and Miller allege relates to the procedures followed by the FDA. They claim that “the FDA is failing to carry out its mission.” [Doc. 19, ¶ 3]. They seek “to put the FDA back on the path to lawful protection of the public in these precarious times.” [*Id.*, ¶ 3]. CHD claims the FDA has “flagrantly violated federal law” and this Court should step in and “vacate . . . the FDA’s decision to license Pfizer’s Comirnaty vaccine and to extend its Pfizer BioNTech” EUA. [*Id.*, pg. 12]. But CHD must have an injury that “affect[s] [it] in a personal and individual way.” *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016) (quoting *Lujan*, 504 U.S. at 560 n.1). That injury must be unique and individualized; the alleged injury cannot be a “collective[] harm” that impacts society generally. *In re Carter*, 554 F.3d 979, 989 (6th Cir. 2009). An “abstract generalized grievance” against illegal behavior that is “suffered by all citizens” does not create standing. *Carney v. Adams*, 141 S. Ct. 493, 499 (2020). Putting the FDA

“back on the path to lawful protection of the public” is such a generalized grievance and not the type of particularized interest or personalized injury necessary to establish Article III standing.

Similarly, members of CHD also do not have standing in their own right. Those members claim that adverse action likely will occur if the military leadership fails to grant their requests for religious accommodation.³ They allege they face court martial, less than an honorable discharge, and exclusion from dining halls and gyms. But all of that is speculative and is not “certainly impending” to constitute an injury for standing purposes. *Clapper*, 568 U.S. at 401-02. Indeed, a majority of the declarants applied for religious exemptions from the mandate but have yet to have their requests denied. None have alleged injuries that have already occurred, only what they believe might occur in the future. But “the mere possibility that the injury will arise in the future does not suffice.” *Ass’n of Am. Physicians & Surgeons*, 13 F.4th at 545 (internal quotations omitted).

The same is true for Plaintiff Miller. She has not alleged a concrete and particularized injury and has not shown that any such injury is fairly traceable to Defendants’ conduct. Miller alleges she faces an “imminent risk of immediate harm” from the FDA’s licensure of the Comirnaty vaccine and reauthorization of the Pfizer-BioNTech EUA. [Doc. 19, ¶ 5]. But she fails to explain what specific harm she faces or whether it is “certainly impending.” *Clapper*, 568 U.S. at 401-02. She does not claim she is subject to a vaccine mandate or that she will face penalties for failing to get vaccinated. Her allegation that she faces a still-to-be-defined harm is not enough

³ Declarants Craymer, Eschmann, Hastriter, Hollowell, Mason, Meacham, Nuss, Raethel, Santos, Sweger, and Zito state that they have applied for vaccine exemptions and have not yet had their exemptions denied. [Docs. 15, pgs. 7, 19, 28, 38-40, 44-45, 52, 85, 125, 130, 174, 183; 20, pgs. 2-3]. Declarants Shour and Stanzone do not state that they are required to take the Pfizer-BioNTech vaccine, and Declarant Perez asserts that his commanders ignored his religious exemption but fails to state whether he complied with the commanders’ instruction to bring documentation of his exemption. [Doc. 15, pgs. 89-92, 133-38, 154-55].

to constitute an injury for Article III standing. *Lujan*, 504 U.S. at 560.

Similarly, her allegation that she has standing through the Citizen Petition fails. The FDA’s denial of the Citizen Petition does not confer standing on Miller because, according to Plaintiffs, Miller did not file a Citizen Petition. [Doc. 19, ¶ 17]. Further, it is unclear how the denial of CHD’s Citizen Petition injures Miller such that it gives her Article III standing, particularly when Plaintiffs do not explain what repercussions Miller faces because of that denial.

Even assuming they have shown an injury, CHD and Miller still fail to satisfy the causation requirement for standing. For causation to exist, the injuries “ha[ve] to be ‘fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.’” *Lujan*, 504 U.S. at 560-61 (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 41-42 (1976)). In this case, the conduct of the FDA “must have a ‘casual connection’ to the plaintiff’s injury.” *Gerber v. Herskovitz*, 14 F.4th 500, 505 (6th Cir. 2021) (quoting *Lujan*, 504 U.S. at 560).⁴ The vaccine mandates, and the potential consequences for refusing those mandates, are not fairly traceable to the specific actions of the FDA. Instead, the various branches of the United States military are imposing the vaccine mandates—not the FDA. [See, e.g., Doc. 15, pgs. 7-16]. Neither the FDA nor Acting Commissioner Woodcock have imposed mandates that impact the declarants. The only actions that Defendants have taken are to license the Comirnaty vaccine and reauthorize the Pfizer-BioNTech EUA. [Doc. 19, ¶¶ 26-52].

⁴ To be sure, “[i]n the nebulous land of ‘fairly traceable,’ where causation means more than speculative but less than but-for, the allegation that a defendant’s conduct was a motivating factor in the third party’s injurious actions satisfies the requisite standard.” *Parsons v. United States Dep’t of Justice*, 801 F.3d 701, 714 (6th Cir. 2015) (holding plaintiffs established standing when the FBI designated their group as a gang because that designation motivated state authorities to violate their constitutional rights). But here, Plaintiffs have not sufficiently alleged that the FDA’s decisions to license the Comirnaty vaccine or give EUA status to Pfizer-BioNTech’s vaccine was the motivating factor in the military’s decision to impose vaccine mandates.

The harms the declarants identify—being subject to vaccine mandates by various branches of the military and the consequences of refusing to comply with those mandates—are tied to the actions of the military leadership and not the FDA.

Moreover, the line of causation between the FDA’s actions and the imposition of vaccine mandates is simply too attenuated to satisfy the causation requirement. Where causation is too attenuated, there is no standing. An example of this is found in *Allen v. Wright*, where the Internal Revenue Service (IRS) refused to deny tax-exempt status to racially discriminatory private schools. *Allen v. Wright*, 468 U.S. 737, 739-40 (1984), *abrogated on other grounds by Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014). The parents of African-American children filed suit claiming that the IRS’s failure to act harmed them and prevented their children from receiving an education in desegregated public schools. *Id.* at 740. The Court found the parents lacked standing because they could not show that their injury was fairly traceable to the IRS. *Id.* at 756-57. The “line of causation between [the IRS’s conduct] and desegregation of [the plaintiff’s] schools [was] attenuated at best.” *Id.* at 757. The Court explained that the “injury to [plaintiffs] [was] highly indirect and result[ed] from the independent action of some third party not before the court.” *Id.* (internal quotations omitted). The Court noted that it was “entirely speculative . . . whether withdrawal of a tax exemption from any particular school would lead the school to change its policies.” *Id.* at 758.

The same is true here. The declarant’s purported injury “results from the independent action of some third party not before the court,” thereby making the “line of causation between [Defendants’ conduct] and [the declarant’s injury] attenuated at best.” *Allen*, 468 U.S. at 757. And, even if the FDA’s actions may have influenced the decision of the military, *see Parsons*, 801

F.3d at 714, the Plaintiffs have not alleged the FDA's actions were a "motivating factor" in the military's decision to impose vaccine mandates.

Even assuming Plaintiff could show injury and causation, they still fail to show their injuries are redressable by a favorable court decision. "[I]t must be 'likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.'" *Gerber*, 14 F.3d at 505 (quoting *Lujan*, 504 U.S. at 560). In this case, Plaintiffs must show that granting the relief sought would actually redress their alleged injuries. Assuming that the Court enjoins Defendants and requires them to revoke the Comirnaty vaccine license, Plaintiffs injuries are still not redressed. The Pfizer-BioNTech EUA remains in place, and the third parties instituting the vaccine mandates, here the various branches of the military, can continue requiring servicemembers to get vaccinated as a condition of employment. Indeed, Secretary Austin's memorandum notifying servicemembers of the impending vaccine mandate clearly states that he would seek to impose a vaccine mandate "no later than mid-September, or immediately upon [the FDA's] licensure, *whichever comes first*." Memorandum from Sec'y of Def. Lloyd Austin to Dep't of Def. employees (Aug. 9, 2021) (available online) (emphasis added). The vaccine mandate is not tied to actions of the FDA. Thus, neither Plaintiff can show their purported injuries would be redressable by a favorable ruling.⁵

⁵ Additionally, as to CHD's alleged organizational standing, Plaintiffs' amended complaint does not assert that CHD was injured by having to divert resources to oppose Defendants' actions, which is required to show organizational standing. *Online Merchants Guild v. Cameron*, 995 F.3d 540, 547 (6th Cir. 2021). The amended complaint's failure to state that CHD diverted resources to oppose Defendants' actions is fatal because, under a Rule 12(b)(1) facial attack, the Court is limited to addressing the sufficiency of Plaintiffs' complaint. *Cartwright*, 751 F.3d at 759-60. Indeed, Plaintiffs only reference a diversion of resources in their Reply brief [Doc. 25, pg. 17]. Thus, Plaintiffs have not shown that CHD has organizational standing to bring the present suit.

III. CONCLUSION

Plaintiffs lack Article III standing to bring suit against Defendants, and the Court lacks subject matter jurisdiction to address the merits of Plaintiffs' claims. Accordingly, Plaintiffs' motions for a "stay" [Docs. 9, 14] are **DENIED**, and Defendants' motion to dismiss [Doc. 22] is **GRANTED**, and Plaintiffs' complaint is **DISMISSED**. A separate judgment shall enter.

SO ORDERED:

s/ Clifton L. Corker
United States District Judge